

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Keller Orthotics, Inc.
Docket No. A-14-48
Decision No. 2588
August 20, 2014

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Keller Orthotics (Keller Orthotics or Petitioner), a company in Chicago, Illinois that was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), requests review of an Administrative Law Judge (ALJ) decision dated January 16, 2014. *Keller Orthotics*, DAB CR3085 (2014) (ALJ Decision). The ALJ affirmed the determination of the Centers for Medicare & Medicaid Services (CMS) to revoke Keller Orthotics' Medicare billing privileges and related supplier number, effective April 9, 2013. The ALJ concluded that CMS had a legitimate basis to revoke Keller Orthotics' Medicare enrollment because the undisputed facts established that the facility was not "accessible and staffed" during its posted hours of operation on that date in violation of 42 C.F.R. § 424.57(c)(7)(i)(C) (Supplier Standard 7). Based on the same facts, the ALJ further concluded that there was an additional basis for CMS to revoke Keller Orthotics' billing privileges under 424.535(a)(5)(ii) because the facility was not "operational" as defined in 42 C.F.R. § 424.502.

As discussed below, we conclude that the ALJ properly affirmed CMS's revocation of Keller Orthotics' Medicare billing privileges pursuant to 42 C.F.R. § 424.57(e) because the facility admitted that it was not staffed on April 9 during an attempted on-site review by a CMS contractor and, therefore, was not in compliance with DMEPOS Supplier Standard 7. However, we also conclude that the ALJ erred in determining that CMS had a basis to revoke under section 424.535(a)(5)(ii) based upon a finding that the facility was not operational. *See* 42 C.F.R. § 498.5(1)(2).

Because the effective date for the revocation here was based on a provision that applied only to revocation on the latter basis, we modify the effective date of the revocation to June 3, 2013 in accordance with section 424.57(e), which governs the effective date of instances of noncompliance with any of the Supplier Standards set forth in section 424.57(c).

Applicable Law

Pursuant to section 1834(j)(1)(A) of the Social Security Act (Act),¹ a DMEPOS supplier may not be reimbursed for items provided to an eligible Medicare beneficiary unless the supplier has a supplier number issued by the Secretary of the U.S. Department of Health & Human Services. To receive a supplier number, a DMEPOS supplier must meet each of the supplier enrollment standards set forth in 42 C.F.R. § 424.57(c)(1) - (30). Among other things, Supplier Standard 7 requires a that DMEPOS supplier must maintain a physical facility on an appropriate site which is in a location that is accessible to the public, staffed during posted hours of operation, and maintained with a visible sign and posted hours of operation. Section 424.57(c)(7). The regulation set forth at 42 C.F.R. § 424.57(c)(10) (Supplier Standard 10) requires a supplier to have a comprehensive liability insurance policy in the amount of at least \$300,000 that is in effect “at all times.” Also, a DMEPOS supplier must permit CMS or its agent to conduct on-site inspections to determine supplier compliance with each of the enrollment standards. 42 C.F.R. § 424.57(c)(8). CMS may revoke a currently-enrolled Medicare supplier's billing privileges if CMS or its agent determines that the supplier fails to meet any supplier enrollment standard. Section 424.57(e); *see also* section 424.535(a)(5)(ii) (reasons for revocation include a “supplier has failed to satisfy any or all of the Medicare enrollment requirements”). Section 424.57(e) also provides that the effective date of revocation for noncompliance with any of the enrollment standards under section 424.57(c) is 30 days after the supplier is sent notice of the revocation. *See* 75 Fed. Reg. 52,629, 52,648-52,649 (Aug. 27, 2010).²

In addition, if an on-site review reveals that a supplier is “no longer operational[,]” CMS may revoke the supplier’s Medicare billing privileges. Section 424.535(a)(5)(ii). A provider or supplier is operational if, among other things, it “has a qualified physical practice location, is open to the public for the purpose of providing health care related services, is prepared to submit valid Medicare claims, and is properly staffed, equipped, and stocked . . . to furnish [the] items or services [being rendered].” 42 C.F.R. § 424.502. The effective date of revocation on this basis is the date CMS determines the supplier was “no longer operational” as a result of an on-site review. 42 C.F.R. § 424.535(g).

¹ The current version of the Act can be found at www.ssa.gov/OPHome/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

² *See Neb Group of Arizona (Neb Group)*, DAB No. 2573, at 7-8 (2014) (explaining the history of the redesignation of section 424.57(d) as currently contained in the Code of Federal Regulations to a revised section 424.57(e)); *accord Benson Ejindu, d/b/a Joy Medical Supply (Joy Medical)*, DAB No. 2572, at 9-10 (2014).

Case Background³

On April 1, 2013, an inspector from the National Supplier Clearinghouse (NSC), a CMS contractor, attempted to conduct an unannounced site inspection at Keller Orthotics' facility located at 1611 West Harrison Street, Suite 109, Chicago, Illinois. CMS Ex. 4, at 14. According to the inspector's report, this attempt was made at approximately 2:27 p.m. during the facility's posted hours of operation (Monday through Friday: 8:00 a.m. to 4:30 p.m.) and the "office was closed." CMS Ex. 4, at 14-15, 19. On April 9, 2013, at approximately 10:56 a.m., the NSC inspector visited the facility at 1611 West Harrison Street location for a second time during its posted hours of operation and noted in her investigative report that: "Second attempt office was closed knock no answers. Lights off." CMS Ex. 4, at 14, 19.

In a letter dated May 3, 2013, the NSC contractor, Palmetto GBA, informed Keller Orthotics that its Medicare billing privileges were being revoked, effective April 9, 2013 with a re-enrollment bar of two years. CMS Ex. 4, at 1. The letter stated that the revocation was based upon a violation of Supplier Standard 7 because "the facility was closed during posted hours of operation." *Id.* at 2. The letter further stated that "we have determined that your facility is not operational to furnish Medicare covered items and services . . . in violation of 42 C.F.R. § 424.535(a)(5)(ii) and all supplier standards as defined in 42 C.F.R. § 424.57(c)." *Id.* In addition, the May 3 letter stated that Keller Orthotics was not in compliance with Supplier Standard 10, 42 C.F.R. § 424.57(c)(10), because "[t]he liability insurance policy . . . on file with the NSC expired on March 1, 2012." CMS Ex. 4, at 2. Finally, the letter stated that "[p]ursuant to 424.535(c), [Keller Orthotics] is barred from re-enrolling for a period of two (2) years in the Medicare program from the effective date of the revocation." *Id.* at 1.

In a letter dated May 9, 2013, Keller Orthotics requested reconsideration and submitted documentation in support of its position that its facility was open and staffed on April 1, 2013. CMS Ex. 3. In its May 9 letter, Keller Orthotics submitted a statement from two of its employees – GK and FR – one of whom (FR) stated that he was present when the NSC inspector attempted her first on-site review on April 1, 2013. P. Ex. E. FR further stated that he called GK and informed him about the on-site review. *Id.* GK states that he spoke with NSC inspector on the telephone and requested that she wait 20 minutes so that he could assist her, but that the NSC inspector indicated that she could not wait and would return at a later date. *Id.* Regarding the second attempted on-site review on April 9, 2013, Keller Orthotics represented to the Medicare hearing officer that "the office staff

³ The factual information in this section, unless otherwise indicated, is drawn from undisputed findings of fact in the ALJ Decision and undisputed facts in the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

was out of the 1611 W. Harrison location due to a staff meeting at our Main facility.” CMS Ex 3, at 2. Keller Orthotics also attached a copy of the Minutes of the staff meeting. *Id.* at 5; CMS Ex. 1, at 3. In its request for reconsideration, Keller Orthotics submitted a certificate of liability insurance in an attempt to demonstrate compliance with Supplier Standard 10. P. Exs. A and B.

In a letter dated June 24, 2013, a Medicare hearing officer with Palmetto GBA issued an unfavorable reconsideration decision stating that “Keller Orthotics, Inc. has not shown compliance with supplier standards 7 and 10.” CMS Ex. 1, at 4. Specifically, the hearing officer found that the case file and additional information submitted by Keller Orthotics “does not verify compliance with supplier standard 7, and the NSC is deemed appropriate in their revocation” *Id.* The Medicare hearing officer also found that Keller Orthotics did not show compliance with Supplier Standard 10 because the certificate of insurance submitted by the supplier showed only a policy with effective dates of March 1, 2013 through March 1, 2014. CMS Ex. 1 at 3. According to the hearing officer, the submitted information “does not verify that liability insurance was current, but rather that there is a policy currently in force.” *Id.*

Keller Orthotics timely filed an appeal with an ALJ on August 13, 2013. Pursuant to the ALJ’s Acknowledgment and Pre-hearing Order (Order), the parties each submitted briefs and accompanying exhibits. ALJ Decision at 2. Neither party submitted written direct testimony for any proposed witnesses, though Keller Orthotics included a joint statement from two of its employees that it had previously submitted with its request for reconsideration. *Id.* citing P. Ex. E. Keller Orthotics did not seek to cross-examine the NSC inspector, and CMS did not ask to cross-examine the two Keller Orthotics’ employees. ALJ Decision at 2. Accordingly, the ALJ issued his decision based on the written record. *Id.*

ALJ Decision

The ALJ affirmed CMS’s revocation of Keller Orthotics’ Medicare billing privileges, though he narrowed the factual and legal basis for the revocation. The ALJ made the following findings of fact and conclusions of law.

1. The ALJ concluded that Keller Orthotics’ location at 1611 West Harrison Street, Suite 109 in Chicago, Illinois was “open and staffed” when an NSC inspector attempted to conduct a site inspection on April 1, 2013, but the NSC inspector decided to return to conduct the inspection on another date. ALJ Decision at 3-4. The ALJ found that the written statement of the two employees from Keller Orthotics “outweighs the limited evidence CMS presents.” *Id.* at 3.

2. The ALJ concluded that Keller Orthotics’ location at 1611 West Harrison Street, Suite 109, Chicago, Illinois was “not open, accessible, and staffed” when an NSC inspector attempted to conduct a site inspection on April 9, 2013. *Id.* at 4. The ALJ found no evidentiary support for Keller Orthotics’ representation before him that during

the second attempted on-site review, “the office was open . . . [but] the staff member took a break when the surveyor attempted to conduct the visit . . . and was to return at noon.” ALJ Decision at 5 n.3 citing; *see* P. Pre-Hearing Brief and Motion for Summary Judgment at 5, 7; *see also id.* Indeed, the ALJ found that this quoted statement was contradicted by Keller Orthotics’ own statements in the request for reconsideration and in its hearing request before him where Keller Orthotics represented that its employees were attending a staff meeting at its main site on that date. ALJ Decision at 5 n.3; *see also* CMS Ex. 3 at 2, 5; CMS Ex. 1, at 3.

3. The ALJ concluded that CMS had a legitimate basis to revoke Keller Orthotics’ Medicare billing privileges because the facility’s location was “not accessible and staffed” during posted hours of operation when an NSC inspector attempted to conduct an on-site review of the facility on April 9, 2013, and was not operational, as required by 42 C.F.R. §§ 424.57(c)(7) and 424.535(a)(5). ALJ Decision at 5.

4. The ALJ concluded the additional documents that Keller Orthotics submitted in its request for reconsideration demonstrated that it was in compliance with the requirements of Supplier Standard 10 in that it had purchased a comprehensive insurance policy in excess of \$300,00 that was in effect when the NSC inspector attempted to conduct a site review of the facility on April 9, 2013. *Id.* at 7.

Standard of Review

The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *See Guidelines — Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program* (Guidelines) available at <http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html>.

Analysis

On appeal, Keller Orthotics challenges the ALJ’s conclusions that it was not in compliance with Supplier Standard 7 on April 9, 2013, or operational on that date.⁴ Keller Orthotics also argues that the two year reenrollment bar should be reduced pursuant to 42 C.F.R. § 424.535(a)(10)(ii). Below, we explain why we reject Keller Orthotics’ argument as to its compliance status as well as its argument with respect to the re-enrollment bar. We also explain why we modify the effective date of the revocation to June 3, 2013.

⁴ CMS did not appeal the ALJ’s admission of the evidence submitted by Keller Orthotics or his conclusion that Keller Orthotics was in compliance with Supplier Standard 10. Accordingly, we do not address the evidentiary ruling or the ALJ’s legal conclusion.

1. The ALJ properly sustained the revocation of Keller Orthotics' Medicare Billing privileges based upon its noncompliance with the requirements of Supplier Standard 7 pursuant to section 424.57(e).

Based on the undisputed facts in this case, the ALJ correctly concluded that Keller Orthotics' practice location at 1611 West Harrison Street, Suite 109 in Chicago, Illinois was not accessible and staffed on April 9, 2013 during its posted office hours based on the facility's admission of facts that demonstrate its noncompliance with the requirements of Supplier Standard 7. ALJ Decision at 5. As noted above, Keller Orthotics stated before the Medicare hearing officer during the reconsideration stage that – “When the representative of NSC attempted to conduct a visit of our facility on 4/9/2013, the office staff was out of the 1611 W. Harrison location due to a staff meeting at our Main facility.” CMS Ex 3, at 2. Before the ALJ, Keller Orthotics stated that when the NSC inspector knocked on the door of its facility at the 1611 West Harrison Street location on April 9, 2013 during its posted business hours, the only staff member at the location had “stepped out of the office for a break and was to return at noon.” P. Pre-Hearing Br. and MSJ at 5, 7; *see also* Request for Review (RR) at 6 (disagreeing with the ALJ's conclusion “based on the fact that the staff member was at the location and stepped out of the office for a break and was to return at noon.”). Although these factual assertions by Keller Orthotics regarding the circumstances of the employee's absence are contradictory, they nevertheless unequivocally show that no member of Keller Orthotics' staff was present at the facility during the second attempted on-site review.⁵

Because Keller Orthotics admittedly was not accessible and staffed when the NSC inspector attempt to conduct an on-site review during its posted hours of operation on April 9, 2013, the ALJ properly concluded that Keller Orthotics' did not meet the requirements of section 424.57(c)(7)(i)(C). ALJ Decision at 5-6; *Neb Group*, at 5-6 (sustaining supplier's revocation for noncompliance with section 424.57(c)(7) because it “admittedly was not accessible and staffed when the NSC inspector attempted to conduct an on-site review during its posted hours of operation . . .”). *See Complete Home Care, Inc.*, DAB No. 2525, at 5 (2013) (“The ALJ correctly concluded that a facility does not meet [the] requirement [set forth in Supplier Standard 7] if it is temporarily closed during its posted hours of operation.”). With respect to accessibility, there is no evidence that the facility posted a notice specifying an alternative method for the NSC inspector (or a

⁵ The ALL found that there was no evidentiary support in the record that the facility was open or that one of Keller Orthotics' employees was present on April 9, 2013 during the second attempted on-site review. ALJ Decision at 5 n.3. Indeed, the ALJ found that this quoted statement was contradicted by Keller Orthotics' own statements in the request for reconsideration and in its hearing request before him where Keller Orthotics represented that its employees where attending a staff meeting at its main site on that date. *Id*; *see also* CMS Ex. 3 at 2, 5; CMS Ex. 1, at 3.

Medicare beneficiary) to request and obtain prompt access to the facility. *See* CMS Ex. 4, at 19; ALJ Decision at 5 citing *Complete Home Care, Inc.*, at 6; *see also Joy Medical Supply*, at 7-8. Section 424.57(e) empowers CMS to revoke the Medicare billing privileges of a supplier that is found not to meet the Medicare enrollment standards established by section 424.57(c). Failure to meet even one supplier standard is a sufficient basis for CMS to revoke a supplier's Medicare billing privileges under section 424.57(e). *1866ICPayday*, DAB No. 2289, at 13. Thus, the ALJ's conclusion that Keller Orthotics was not staffed and accessible within the meaning of section 424.57(c)(7) is supported by substantial evidence in the record and is free from legal error. Accordingly, we conclude that the ALJ properly sustained the revocation of Keller Orthotics' Medicare billing privileges based upon its noncompliance with the requirements of Supplier Standard 7 pursuant to section 424.57(e).

2. Because the reconsideration decision made no finding that Keller Orthotics was not operational, the ALJ erred in determining there was a basis to revoke on the alternative ground that it was not operational as defined in section 424.502.

Based upon the same set of facts discussed above, the ALJ also concluded that CMS had a legitimate basis to determine that Keller Orthotics was not operational within the meaning of section 424.502 as of April 9, 2013, the date of the second attempted inspection. Therefore, the ALJ found there was also a basis for revocation under section 424.535(a)(5)(ii). ALJ Decision at 5-6. Although CMS's initial determination (May 3, 2013) stated that Keller Orthotics was not operational, the Medicare hearing officer's reconsidered decision did not. CMS Ex. 1, at 3. Keller Orthotics' right of appeal was from the reconsidered determination, not the initial determination. 42 C.F.R. § 498.5(l)(2); *see also Neb Group of Arizona*, at 5-6; *Joy Medical Supply*, at 5. The reconsidered determination stated only that "Keller Orthotics has not shown compliance with supplier standards 7 and 10" as the legal basis for Petitioner's revocation. CMS Ex. 1, at 3. Thus, the only issue properly before the ALJ was whether there was a legal basis for revocation of Keller Orthotics' billing privileges pursuant to section 424.57(e), not whether Keller Orthotics was not operational and thereby subject to revocation under section 424.535(a)(5)(ii). Accordingly, the ALJ did not have the authority to conclude that Keller Orthotics' Medicare billing privileges could additionally be revoked on the ground that it was not operational.

3. We reject Keller Orthotics' argument that section 424.535(a)(10)(ii) would apply even if the Board were to conclude that ALJs and the Board are authorized to alter the length of a re-enrollment bar.

On appeal, Keller Orthotics alleges that under 42 C.F.R. § 424.535(a)(10)(ii), the re-enrollment bar should be reduced to one year because only one noncompliance issue is pending. RR, at 7. We note at the outset that this argument assumes that the length of a

re-enrollment bar is subject to review by ALJs and the Board. The Board has not addressed that issue and, we need not do so here because 424.535(a)(10)(ii) would not apply in this case even assuming such authority.

The cited regulation states:

Failure to document or provide CMS access to documentation.

(i) The provider or supplier did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

As CMS correctly points out, this regulation applies only where the noncompliance found is based upon the failure of a supplier to provide CMS access to documentation that section 424.516(f) requires must be maintained.

Our decision here sustains the ALJ's determination that Keller Orthotics was not in compliance with the Supplier Standard 7. Neither CMS nor the ALJ found that Keller Orthotics failed to maintain or provide CMS access to the documentation required by section 424.516(f). Accordingly, section 424.535(a)(10)(ii) would not apply in this case even assuming that the ALJs and the Board had authority to reduce the length of a re-enrollment bar.⁶

4. Under section 424.57(e), the correct effective date for the revocation of Keller Orthotics' Medicare billing privilege based on its failure to meet the requirements of Supplier Standard 7 is June 3, 2014.

In light of our decision to sustain the revocation of Keller Orthotics' Medicare billing privileges solely based on the facility's noncompliance with Supplier Standard 7, we find it necessary to modify the effective date of that revocation. In its May 3, 2013 notice of revocation, CMS advised Keller Orthotics that its revocation date was made retroactive to April 9, 2013 based upon its determination that its Keller Orthotics' practice location was "not operational" on that date. CMS Ex. 4, at 30. In choosing the effective date, CMS

⁶ In any event, Keller Orthotics did not clearly dispute before the ALJ that the length of the re-enrollment bar should be reduced though Keller Orthotics could have reasonably anticipated that the ALJ might find in its favor on one of the multiple bases given for the revocation in the reconsideration decision. Nonetheless, Keller Orthotics did not argue in the alternative that if the ALJ upheld the revocation on fewer bases, he should reduce the length of the re-enrollment bar. Under the Board's Guidelines, "the Board will not consider issues which could have been presented to the ALJ but were not." *Complete Home Care, Inc.*, at 5 citing Guidelines; *Better Health Ambulance*, DAB No. 2475, at 4 n.4 (2012).

was apparently applying the provisions of section 424.535(g). That regulation states a general rule that the effective date of a revocation is 30 days from the date CMS mails the supplier notice of its revocation determination. However, if CMS issues a revocation based on section 424.535(a)(5)(ii), which requires a finding that the supplier is “no longer operational,” then section 424.535(g) provides that the effective date is the “date that CMS or its contractor determined that the provider or supplier was no longer operational.” As previously discussed, that exception cannot properly be applied in this case.

Because the sole basis for revocation in this case is Keller Orthotics’ acknowledgement that it was not staffed and accessible on April 9, 2013 when the NS inspector attempted her second on-site review as required by Supplier Standard 7, the effective date of revocation should be determined in accordance with section 424.57(e)’s effective-date provision. As we recently discussed in *Neb Group of Arizona*, at 7-8 and *Joy Medical Supply*, at 8-10, section 424.57(d) in the Code of Federal Regulations currently states that a revocation based on a violation of section 424.57(c) “is effective *15 days* after the [supplier] is sent notice of the revocation” (italics added). The regulation’s editorial note states that a January 2, 2009 final rule (74 Fed. Reg. 198) re-designated paragraph (d) of section 424.57 as paragraph (e) but that this and other changes to section 424.57 were not incorporated into the codified text of the regulation because of an “inaccurate amendatory instruction.” Also, on August 27, 2010, CMS published a final rule in the Federal Register which revised paragraph (e) (that is, the re-designated paragraph (d)) to extend the effective date of a revocation based on section 424.57(c) *from 15 to 30 days* after the supplier is notified of the revocation. Final Rule, *Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards*, 75 Fed. Reg. 52,629, 52,648-52,649 (Aug. 27, 2010). Applying that rule here, we conclude that the proper effective date of the revocation is June 3, 2013.

Conclusion

For the reasons discussed above, we affirm the ALJ Decision to uphold the revocation of Keller Orthotics' Medicare billing privileges based upon its noncompliance with the requirements of section 424.57(c)(7)(i)(C), but we modify the effective date of the revocation to June 3, 2013.

_____/s/
Sheila Ann Hegy

_____/s/
Leslie A. Sussan

_____/s/
Stephen M. Godek
Presiding Board Member